



DOCKET NO: 217151US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :
AKIRA YAZAKI, ET AL. : EXAMINER: MORRIS, P.
SERIAL NO: 10/019,436 :
FILED: DECEMBER 31, 2001 : GROUP ART UNIT: 1625
FOR: QUINOLINECARBOXYLIC ACID :
DERIVATIVE OR SALTS THEREOF

DECLARATION UNDER 37 C.F.R. § 1.132

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Now comes Akira Yazaki, who deposes and states that:

1. I am an inventor in the above-identified application.
2. I have been employed by Wakunaga Pharmaceutical Co., Ltd. as a chemical researcher 27 years in the field of drug discovery (anti-infectives)
3. I received my Doctor's degree in Chemistry from Kyoto university in year 1982
4. I have read and understand the above-identified application, and I am thoroughly familiar with its contents.
5. I have read and understand U.S. Patent No. 5,998,436 to Yazaki et al., and I am thoroughly familiar with its contents.
6. I have read and understand the Office Action mailed August 8, 2003, in the above-identified application or that its contents have been explained to me such that I thoroughly understand them.

7. That to show that the present invention is drawn to a patentable selection invention, which is not disclosed or suggested in the Yazaki et al. patent, the following comments and opinions are submitted for her consideration.

8. The Examples, Referential Examples, and Preparative Examples shown and discussed at pages 16-26 of the above-identified application are actual examples, which are based on actual experiments carried out either by me or under my direct supervision and instruction. Other than the results disclosed therein, there are no exemplary or comparative results that have not been disclosed to the Examiner which would portray the present invention in an unfavorable manner. The methods and tasks disclosed therein to determine the anti-microbial effects, phototoxicity, antibacterial effects, and *in vivo* pharmacokinetic effects are art-recognized methods and tests, which provide statistically significant results. The results observed for the examples and comparative examples are statistically significant, and differences observed between the comparative and invention examples are statistically significant differences. The improvements observed for the present invention are both unpredictable and surprising in view of the disclosure in Yazaki et al.

9. The present invention is completely enabled by the supporting disclosure. As noted, for example, in Table 1 on page 22 of the specification, the present invention exhibits a clear antimicrobial effect *in vitro*. Further, as noted in the disclosure at page 1 of the specification, compounds having the basic skeleton of quinoline-carboxylic acid are known to include many compounds useful as synthetic antimicrobials and therapeutic agents for infections diseases, and thus a reasonable correlation exists between the exhibited *in vitro* data and expected *in vivo* results.

10. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

11. Further deponent saith not.

Akira Yazaki
Signature

Akira Yazaki
Printed Name

Dec. 10, 2003
Date